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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/990,377      | 11/23/2001  | Qiang Li             | 215752US20          | 2849             |

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EXAMINER

MILLER, MARTIN E

ART UNIT

PAPER NUMBER

2623

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |              |
|------------------------------|-----------------|--------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s) |
|                              | 09/990,377      | LI ET AL.    |
|                              | Examiner        | Art Unit     |
|                              | Martin Miller   | 2623         |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) 1-19 is/are rejected.

7) Claim(s) \_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 23 November 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 has cited the references, they have not been considered.
2. Applicant is requested to submit any of the listed reference patents or publications that have particular relevance to the disclosed invention.

### ***Drawings***

3. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 8, 11-14, 17-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Komiya et al., (hereinafter Komiya), US 5,754,676.

As per claim 1, Komiya teaches:

obtaining a medical image having a candidate abnormality (input image, col. 6, ll. 55-56, Ultrasonic image, col. 26, l. 15);

segmenting the candidate abnormality in the medical image (segmentation is performed by the medical doctor when he selects the region of interest, col. 26, ll. 16-19);

extracting at least one predetermined feature (col. 8, ll. 27-30, col. 26, ll. 31-34) from the segmented candidate abnormality;

comparing the candidate abnormality with plural database abnormalities including known malignant abnormalities and known benign abnormalities (determined from the learning steps of the neural network), including comparing the at least one extracted feature from the at least one candidate abnormality with corresponding extracted features extracted from the database abnormalities (col. 13, ll. 12-24, 46-55, the comparison is performed by a comparison of the final classification number to class classification number);

identifying, based on the comparing step, at least one database malignant abnormality and at least one database benign abnormality having similarity to the candidate abnormality (col. 16, ll. 19-25); and

displaying the database abnormalities identified in the identifying step (fig. 22).

As per claim 8, Komiya teaches:

obtaining a CT medical image (col. 21, l. 56-col. 22, l. 10).

As per claim 11, Komiya teaches:

using an artificial neural network (ANN) (col. 26, ll. 39-44, figure 18, element 56c); and determining a similarity measure based on an output of the ANN (col. 26, ll. 45-51).

As per claim 12, Komiya teaches:

using an ANN having at least three levels (input, intermediate, output, figure 18, element 56c).

As per claim 13, Komiya teaches:

identifying at least one similar malignant database abnormality and at least one benign abnormality based on an output of the ANN (col. 26, ll. 49-54); and  
displaying the database abnormalities identified in the identifying step (figure 22).

As per claim 14, Komiya teaches:

wherein the displaying step comprises displaying at least one candidate abnormality with at least one malignant abnormality and at least one benign abnormality on a common display (figure 22, col. 22, ll. 14-32).

As per claim 17, Komiya teaches:

displaying at least one candidate abnormality with at least one malignant abnormality and at least one benign abnormality on a common display (fig. 22, col. 16, ll. 19-24).

As per claim 18, Komiya teaches:

A system implementing the method of any one of Claims 1 through 17 (fig. 4).

As per claim 19, Komiya teaches:

A computer program product storing program instructions for execution on a computer system, which when executed by the computer system, cause the computer system to perform the method recited in any one of Claims 1 through 17 (fig. 4).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 2623

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2- 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komiya and Giger et al., (hereinafter Giger), US 5,984,870.

As per claim 2, Komiya does not specifically teach:

extracting at least one feature from the group comprising effective diameter, contrast, degree of irregularity, pixel standard deviation, radial gradient index (RGI);

But Komiya teaches a "circularity calculator" (col. 21, ll. 2-6) which to one of ordinary skill would be a degree of circularity. Additionally, Komiya teaches conducting a CT test (col. 21, l. 13), which can be used to provide a computed tomography (CT) value, and determines the length of the contour of a malignant or benign tumor (col. 20, ll. 6-15, 49-50), this could be used by one of ordinary skill in the art to determine an "effective" diameter.

However, Giger specifically teaches extracting features to compute a radial gradient index (RGI) (col. 7, l.13-col. 8, l. 10).

It would have been obvious to one of ordinary skill in the art to use the RGI of Giger or the circularity calculator or CT test of Komiya to determine features that can be used to distinguish between malignant and benign features thereby decreasing patient morbidity as well as the number of surgical biopsies performed and the associated complications.

As per claims 3 and 5, they recite substantially the same limitations as claim 2 above, except they recite, "extracting at least two features" and "extracting at least three features", respectively. The Examiner believes that one of ordinary skill in the art would use the suggestion of Komiya that different features can be used to make a determination of malignancy

or benignancy. It would be up to the system designer to determine if they were confident using one feature to determine malignancy or benignancy or that a combination of features would provide increased accuracy and greater probability of a correct classification.

As per claim 4, it narrows claim 3 even further by limiting the two features to effective diameter and CT value. However, Komiya teaches determining the length of the contour of a malignant or benign tumor (col. 20, ll. 6-15, 49-50), this data clearly could be used by one of ordinary skill in the art to determine an "effective" diameter. Also, Komiya teaches conducting a CT test, col. 21, l. 13, which would return a result that could be classified as a CT value. Therefore, It would have been obvious to one of ordinary skill in the art to use the contour line data and a result from the CT test of Komiya to determine the claimed features that would indicate malignancy or benignancy.

As per claim 6, it recites the same limitations as claim 4 above except it also includes the RGI feature as taught by Giger (col. 7, l. 13-col. 8, l. 10). It would have been obvious to one of ordinary skill in the art to use the contour line data and a result from the CT test of Komiya to determine the claimed features that would indicate malignancy or benignancy.

8. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komiya, as applied to claim 11 above, and further in view of Guha, US 5373452.

As per claim 15, Komiya teaches using the name of abnormal portion as input by the teacher, col. 12, ll. 48-52, to assist in the feature extraction. But Komiya does not specifically teach that a subjective rating is used in the determination of similarity. However, Guha teaches using such a feature in a neural network environment. Therefore, Guha teaches:

training the ANN based on at least one subjective similarity rating ( col. 1, ll. 14-22, col. 4, ll. 26-35).

It would have been obvious to one of ordinary skill in the art to use the subjective intangible property of Guha as one of the inputs into the neural network of Komiya to capture the relationship between the subjective property and measurable physical properties of the feature under test because neural network models are inherently fault tolerant due to the distributive fashion in which they represent data (Guha, col. 1, ll. 51-55).

As per claim 16, Guha teaches:

using an ANN trained at least in part by means of at least one subjective similarity rating (col. 4, ll. 41-44.)

9. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komiya, as applied to claim 1 above, and further in view of Yoshida et al. (hereinafter Yoshida), US 6078680.

As per claim 9, Komiya teaches an erosion and dilation to insure better accuracy in the determination of contour lines (col. 20, ll. 30-35). Komiya does not specifically teach the use of region growing. However, Yoshida teaches:

using a region growing technique (col. 3, ll. 34-37).

It would have been obvious to one of ordinary skill in the art to use the well-known region growing techniques of Yoshida as an equivalent substitute for the feature extraction method of Komiya due to the fact that region growing is particularly accurate when a user provides the general outline of the region to be classified (as is the case in Komiya) and there are

expected to be only a few suspicious regions (by having only a few regions the regions will not tend to "grow" into one another).

As per claim 10, Komiya teaches:

region growing from a point included in a manually generated outline (region found by a medical doctor, col. 26, l. 16). It would have been obvious to one of ordinary skill in the art to allow the doctor to manually generate an outline of the region that the doctor thought looked suspicious. Additionally, Komiya teaches that classification is performed for sequentially designated regions (col. 26, ll. 45-46).

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Komiya, as applied to claim 1 above, and further in view of Cabib et al. (hereinafter Cabib), US 5784162.

As per claim 7, Komiya does not specifically teach an absolute difference determination between a candidate and reference feature. However, Cabib teaches:

calculating at least one similarity measure based on an absolute difference between at least one extracted feature (pixel wavelength spectrum) of the candidate abnormality and at least one corresponding feature of a database abnormality (reference spectrum) (col. 9, ll. 28-32, 45-48).

It would have been obvious to one of ordinary skill in the art to use the spectral pixel features as taught by Cabib as a feature to be extracted in the system of Komiya because of the increased signal-to-noise ratio in spectral measurements thus allowing for better extraction of image shapes and more accurate classification.

***Conclusion***

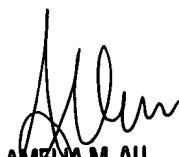
11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following U.S. patent(s) refer(s) to diagnosing diseases in image data: Bamberger et al., US 5970164, and Li et al, US 6470092.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martin Miller whose telephone number is (703) 306-9134. The examiner can normally be reached on Monday-Friday, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on (703) 308-6604. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9314 for regular communications and (703) 872-9314 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3900.

*mlm*  
mem

February 14, 2003



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